REMARKS

The application has been amended and is believed to be in condition for allowance.

Formal Matters and Amendments

Claims 46, 49, 52, 55, 58, 61, 64 and 67 were withdrawn from consideration.

Claims 31-45, 47, 48, 50, 51, 53, 54, 56, 57, 59, 60, 62, 63, 65, 66, and 68-70 were rejected as indefinite.

Claim 31 has been amended to recite "more than 50 vol.% of a mixture of CA and C12A7" as suggested by the Official Action. Claim 31 was also amended to clarify two recitations, i.e., "less than 50 vol.% but at least a non-trace amount to 0 vol.% of CA_2, based on the total volume of the calcium aluminate phases;" and "less than 10 vol.%, but at least a non-trace amount, of C_3A, based on the total volume of the calcium aluminate phases;".

Claim 70 was similarly amended. Claim 70 was also amended to replace the wording "high temperatures" with "temperatures up to 150°C". Support is found on specification page 6, lines 27-29.

Withdrawal of the indefiniteness rejection is therefore solicited.

Thus, the present invention has been restricted to the embodiment featuring all of the phases CA, C12A7, and the phases C3A and CA2 in at least non-trace amounts. The support for amending the claims include:

-page 11, paragraph 6 states that it is of particular interest to include not include CA2 or to use a small amount of it,

-page 12, paragraph 1 states that it is also preferred to include a small amount of C3A, and

-page 7, paragraphs 3 and 4 state that a preferred embodiment comprises the phases CA2 + CA + C12A17 + C3A.

Claim 43 was amended to recite that the amount of CA_2 and the amount of C_3A is selected for achieving temperatures up to 150°C during use and so that the biocompatible ceramic composition generates a controlled amount of heat at temperatures of 30-150°C when cured in a living human body.

Substantive Rejections

Claims 31-33, 36, 39-45, 47, 48, 50, 51, 69, and 70 were rejected as obvious over KAWAHARA et al. 4,652,593.

Claims 34-38, 53, 54, 56, 57, 59, 60, 62, 63 and 65-68 were rejected as obvious over KAWAHARA et al. in view of SE 010441-1 ("SE 441").

Claims 31-33, 36, 39-45, 47, 48, 50, 51, 69 and 70 were rejected as obvious over SE 463,493 ("SE 493").

Claims 34-38, 53, 54, 56, 57, 59, 60, 62, 63, and 65-68 were rejected as obvious over SE 493 in view of SE 441.

Claims 31-45, 47, 48, 50, 51, 53, 54, 56, 57, 59, 60, 62, 63, 65, 66 and 68-70 were rejected as obvious over SE 441.

Why the claims are patentable.

Pages 10-12 of the present application disclose that the CA_2 and C_3A phases are needed in order to maintain the breadth of the temperature interval. The CA_2 phase is particularly suitable for low temperatures and the C_3A for high temperatures.

Providing a biocompatible ceramic material having a sufficient strength and high initial loading capacity, which generates a high but controlled amount of heat during curing, for therapeutic purposes, has previously not been presented in the prior art.

Claim 31 recites "less than 50 vol.%, but at least a non-trace amount, of CA_2". Claim 31 also recites "less than 10 vol.%, but at least a non-trace amount, of C_3A, based on the total volume of the calcium aluminate phases".

As to the applied references, the Official Action has not indicated that it would be obvious to modify them to include C_3A.

The generation of heat when curing a material is previously known from the prior art. In most cases it is a feature of the hardening process that is undesirable, in particular for dental applications. However, no one has previously mentioned that said generated heat could be used for the therapeutic purposes mentioned in the present invention (cancer treatment, pain relief, vascular treatment, bone

restoration and activation of drugs, see page 4, lines 30-31) in a controlled fashion. Being able to control the temperature generation, is something that is very important in order to control damage to surrounding tissues.

None the cited references, nor any other prior art documents acknowledge the use of any generated temperature for the therapeutic purposes according to the present invention, or provide any means to control such a temperature increase.

Before the present invention, no one had previously suggested or demonstrated how these phases could be used in order to achieve temperature control within the temperature interval according to the present invention. In the cited prior art documents (in particular those having the same applicant as the present application) some or all of the phases mentioned in the present invention are described, but none of the documents suggest or demonstrate that the phases could be used for temperature control. Nor do they suggest any suitable concentration intervals for said phases.

SE-010441-1 (belonging to the same applicant) does acknowledge the generation of heat during curing, but presents this as a problem. SE-010441-1 is able to reduce the heat generation by the addition of inert fillers and by reducing the amounts of accelerators used during curing. However, SE-010441-1 does not suggest that the binding phases could be used for temperature control. Nor does SE-010441-1 suggest any suitable

concentration intervals for said phases (due to the fact that the inventors, one of them also being one of the inventors of the present application, did not possess that knowledge at the time).

Moreover, no prior art had previously disclosed a ceramic material which could achieve the temperature control according to the present invention, while achieving the strength requirements for orthopaedic and dental applications.

Thus, heat generation during curing has previously been acknowledged in the prior art as problem. Absent impermissible hindsight, there is no reason one of skill would suddenly consider the idea of using the "disadvantageous heat" generated from the ceramic material for a therapeutic purpose, e.g. for killing cancer, as in the present patent application. The prior art makes no teachings as how to solve the problem of controlling the disadvantageous heat. If the curing reaction is not controlled, the generated biocompatible material will not have the adequate properties for functioning as a biocompatible and strong implant. The heat will kill the cancer, but the uncontrolled heat generation will also destroy surrounding tissue. Accordingly, absent this missing teaching, one of skill would not move in this direction and the invention is non-obvious.

Rather, the solution in the prior art for reducing heat generated during curing of ordinary ceramic materials, has mainly involved adding inert elements which do not generate heat (or as much heat) and provide a ceramic material with sufficient strength

(see for example SE-010441-1, which was not publicly known by that time, now belonging to the applicant, Doxa AB after the merger with Cerbio AB) discloses a ceramic material which may intended for dental and orthopaedic applications, and that may include the same the same phases as described in the present invention. Like the rest of the prior art, SE-010441-1 does not specify any suitable ranges for such phases. SE-010441-1 acknowledges the generation of heat during curing and presents this as a problem. SE-010441-1 limits the heat generation to less than 40°C by using inert fillers such as ternary oxides. The reason is the disclosed phase composition and the amount of inert additives and low concentration of accelerators used. The temperature increase (to therapeutic levels) cannot be controlled unless the composition is as specified in claims 1-3 of the present invention, and the concentration of the processing aids, i.e. accelerators and retarders are as specified in the dependent claims of the present invention.

The inventors of the present invention, which were also involved in the filing of SE-010441-1, were at the time capable of keeping the heat generation during hardening below 40°C by using inert fillers not generating any heat. However, at the filing date of SE-010441-1, the inventors did not possess the knowledge of controlling the temperature within the temperature range of 30-150°C with undiminished strength properties. This is the reason why no information regarding any temperature control in the higher

temperature region is described or hinted in said document. All of the phases in claim 1 (according to present invention) are necessary in order to achieve a controlled temperature generation of 30-150°C and a sufficiently high compression strength that makes it suitable for the therapeutic purposes specified in the application.

In summary, should the person skilled in the art try to solve the problem of performing therapeutic treatment (in contrast to the prior art) by using the heat generated from a prior art ceramic materials, they would end up with a very rapid and strong heat generation resulting in death of surrounding tissue and an insufficiently strong chemically bonded ceramic material. Should the skilled person then resort to using the prior art techniques for reducing the heat generated, by adding elements not generating any heat or generating less heat, he would then end up with a material that may be sufficiently biocompatible but which may lack in strength, and which may not produce sufficient heat or controlled heat generation. He would then face the problem of balancing these ingredients in order to get the correct heat-generation profile. He would perhaps also have to consider additional elements in order to achieve this. The prior art does not teach the skilled person what elements to include, and in which concentrations. The person skilled in the art was therefore not led in the direction of the invention. Moreover, considering the fact that that it took the present inventors (being one of the

leading companies in this field) approximately 9 months from filing of SE-010441-1 to be able to solve this problem, despite the fact that they had knowledge (which was not publicly known at the time of filing of the present application) about the phases which proved to be successful in the present application, the person skilled in the art, should he have been led in the right direction, he would still have had to perform an undue burden in order to reach the present invention. It is thus strongly believed that the present invention is both novel and inventive.

The Present Invention Solution

First of all it should be pointed out that all of phases CA, C12A7, C3A and CA2 are not commercially available phases, but must be synthesised by those who wishes to use them. Some, but not all, of these phases have previously been combined. However, the quantities of each phase have never been those recited.

CA and C12A7 yield reaction rates and general properties suitable for a biomaterial. To increase and moderate the temperature generated, additional phases are used. C3A is used to increase the reaction rate and achieved temperature. This phase can be described as giving the temperature profile a sharp peak. However the content of this phase is restricted to less than 10% in order to not boil the surrounding tissue. The C3A phase does however not create an optimal microstructure, leading to bubbles in the structure, which may reduce the strength with up to as much as 50 %. CA2 is used as a moderator to slow down the reaction

rate, but it also contributes to a long-term hydration resulting in reduced porosity and a stronger material. The hydration of CA2 thus functions as a repair phase, resulting in reduced porosity and greater strength. This phase can be described as giving the temperature profile a more dome-like peak. It is therefore not obvious to create a strong material exhibiting a controlled heat generation. However, by using all these phases, and keeping within the specified amounts of the ceramic phases, optimal temperature increase rate and controlled final temperature can be accomplished. The use of the phases according to above enables the combination of the material both as an implant (injectable) and a source for controlled heat generation.

In view of the above-mentioned arguments and the amendments to claim 31 and 70, applicants believe that the present invention, as recited, is non-obvious.

Applicants believe that the present application is in condition for allowance and an early indication of the same is respectfully requested.

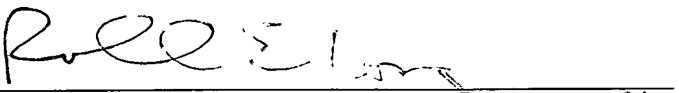
Should there be any matters which can be resolved by telephone, it is requested that the undersigned attorney be contacted in order to discuss any needed items.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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